Original Article

Psychometric Characteristics of the Persian Version of the Irritable Bowel Syndrome Quality of Life Questionnaire (P-IBS-QOL)

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ABSTRACT

Objectives: This study investigated the psychometric characteristics (structural, concurrent and construct validity, and internal consistency) of the Persian version of the Irritable Bowel Syndrome Quality of Life (IBS-QOL) questionnaire, which is commonly used across cultures.

Methodology: One hundred twenty-six patients with irritable bowel syndrome (based on diagnosis by professional physicians and the Rome II criteria) were selected from patients referred to Alzahra and Noor Hospitals in Isfahan to complete the IBS-QOL questionnaire.

Results: Eight subscales of the questionnaire (sum score) had acceptable internal consistency coefficients (alpha for subscales: dysphoria, 0.88; interference with activity, 0.67; body image, 0.72; health worry, 0.57; food avoidance, 0.52; social reaction, 0.71; sexual concern, 0.76; relationships; 0.62; and overall score, 0.93). In order to assess construct validity, groups of healthy persons (n = 40) and patients (n = 40) were selected. Results of an independent t-test showed a significant difference between the mean of overall score and all subscale scores (except body image subscale) of the two groups ($P < 0.05$). Pearson correlation coefficients showed that the questionnaire has significant concurrent validity (with respect to IBS-QOL-36) ($P < 0.05$).

Conclusion: The Persian version of IBS-QOL-34 is a valid and reliable instrument and is suitable for used in research and clinical trials.

KEY WORDS: Irritable bowel syndrome, Quality of life questionnaire, Structural validity, Internal consistency, Concurrent validity, Construct validity.

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INTRODUCTION

Irritable bowel syndrome (IBS) is the most common, the most expensive, and the most disabling of functional gastrointestinal disorders. Its symptoms are abdominal pain or discomfort and change in bowel movement in the absence of diagnosable structural disorders.[1,2]

The expression "quality of life" was primarily introduced into research after World War II with respect to patients with special diseases such as diabetes and AIDS, and specific disabilities.[3,4] A subset of quality of life called "health-related quality of life" (HRQOL) has attracted the interest of researchers and therapists.[5,6] HRQOL relates to patients' perceptions and attitudes to aspects of life that are affected by their disease.[7,8] There is general and increasing agreement that determining HRQOL should be one of the main

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components of therapy and research effort. In the case of functional gastrointestinal disorders, because there are no specific symptoms and signs, assessment of HRQOL is particularly important for the determination of treatment responses and capturing the patients' physical, psychological, and social functions[7-9] In IBS, a chronic disease, quality of life is low and various dimensions of life, such as job activities, traveling, interpersonal relationships, and enjoyment, are disrupted.[10-13]

In recent years researchers and professionals have shown a particular interest in the assessment of quality of life in IBS patients.[14-16] Since there is no specific biological marker and patients and their therapists have different opinions about the illness experience, the most important criterion to determine the level of recovery is assessment of quality of life by the patients themselves. This is only possible by using questionnaires with established validity and reliability and sensitivity to treatment.[9]

In 1998, the first questionnaire about quality of life for IBS patients [the Irritable Bowel Syndrome Quality of Life (IBS-QOL) questionnaire] was published by Patrick and Drossman.[5] Among existing instruments, Patrick and Drossman's questionnaire has been rated as the most valid and reliable, and it has been translated into over 24 languages. The validity and reliability of the European and Asian versions of this questionnaire attest to its value as an international and intercultural instrument.[17-19] Following the WHO method, this questionnaire is based on a needs-oriented model in which quality of life is assessed as the extent to which patients' needs are satisfied.[20] The development of this questionnaire was based on standard principles of psychometric design using established methodology.[17] Quality of life advisers and gastroenterologist from England, Germany, Italy, and France cooperated in the construction of this questionnaire.[21] In exploratory factor analysis of the final version of the questionnaire, eight factors are clearly distinguishable: dysphoria, relationships, sexual concern, health worry, social reaction, body image, food avoidance, and interference with activity. The main questionnaire and its European and Asian versions have always had high internal consistency and test–retest reliability, and special sensitivity and responsiveness to various treatments (medical and psychological therapies).[17,18]

The aim of this study was to investigate the psychometric characteristics (structural, concurrent, and construct validity and internal consistency) of the Persian version of this questionnaire in order to utilize this new version in further research in this country. We therefore tested two major hypotheses:

1. The Persian version of IBS-QOL has an acceptable and desirable internal structure, internal consistency, and construct validity.
2. The Persian version of IBS-QOL has significant concurrent and construct validity.

METHODOLOGY

Participants and procedures: The study population included all patients with IBS in Isfahan who were referred to professional medical centers. The mean age of the patients was 32.34 years (range 18–57 years). First, two skilled translators (two professors from the foreign language faculty of Isfahan University) with the collaboration a gastroenterologist from Isfahan Medical University (to check the translation of medical expressions) translated the original version of IBS-QOL to Farsi and an agreed version of the translation was developed. Then, a native speaker of English, also fluent in Farsi, back-translated it into English. By comparison with forward translation, discrepancies and inaccuracies were removed. Then, a professor from the Persian literature faculty of Isfahan University corrected and confirmed the punctuation of the translation and a final Persian version of the questionnaire (P-IBS-QOL) was prepared.

Fundamental principles (including backward and forward translation and removal of grammatical and structural mistakes) were taken into consideration. The face validity of the questionnaire was evaluated before the subjects were asked to complete the questionnaire. Ten IBS patients were asked to highlight items that were vague or ambiguous. These items were then restructured by two professors of literature from Isfahan University. The 10 patients were then re-interviewed to assure the clarity of rectified items, in order to confirm face validity.

Finally, questionnaires were distributed to focus groups. One hundred thirty patients (74 females and 56 males) who were referred to clinics of the Alzahra and Noor hospitals and were diagnosed with IBS based on the Rome II criteria and clinical and par clinical tests, and who were willing to participate in the study, were selected and asked to complete the Persian translation of IBS-QOL-34 [one criterion was considered in order to select the sample: patients with no other gastrointestinal disease (the questionnaire was developed only for IBS patients)]. Four patients who did not respond completely to the questionnaire (more than four

items) were omitted from the research sample and the final sample comprised 126 participants.

To assess concurrent validity, we needed an instrument that was known to measure QOL accurately and specifically for IBS patients. For this purpose, we selected IBS-QOL-36, which was developed and validated by Groll and colleagues. This questionnaire is a condition-specific instrument that was developed according to systematic and standard methodology and has acceptable psychometric characteristics (see Measures). We translated this questionnaire into Persian and administered it to 40 IBS patients. The results showed that the scale has high internal consistency (0/87). Then, 44 of the patients from the sample were asked to complete IBS-QOL-34 and IBS-QOL-36 (whose validity was also established).

To determine the construct validity of the questionnaire, 40 people who had no history of gastroenterological disorders were selected to complete the quality of life questionnaire. They were 40 employees of Isfahan University and were selected because they had no records of gastrointestinal diseases in the medical files of the health center of Isfahan University, and currently they had no symptoms of any other chronic medical diseases (which might have a negative effect in HRQOL**)**.

Ethics Approval: This study was approved by the ethics committee of the Alzahra General Hospital, Isfahan, Iran. An educational book about IBS (about the etiology and management of the disease, available at Tehran Medical University) was given to the patients to acknowledge their participation in the study.

Measures: The IBS-QOL-34 was developed in 1998 by Patrick and Drossman to assess HRQOL for IBS patients. This questionnaire has special sensitivity to various treatments; it has been translated into several languages and the translated versions are valid and reliable.[17,18] This questionnaire includes 34 items scored on a five-point Likert scale (not at all, 1; slightly, 2; moderately, 3; quite a bit, 4; extremely, 5).[5] This questionnaire has eight subscales: dysphoria, relationships, sexual concern, health worry, social reaction, body image, food avoidance, and interference with activity. Internal consistency coefficients of these subscales were 0.86, 0.83, 0.56, 0.94, 0.76, 0.48, 0.61, and 0.74, respectively and that of the overall scale was 0.94.[21]

The IBS-QOL-36, which was used in this research to assess the concurrent validity of the main questionnaire, was constructed by Groll et al in 2002 and includes 36 items scored on a seven-point Likert scale. The items of IBS-QOL-36 were developed using the Medline database and about irritable bowel syndrome, quality of life, physical symptoms and existed questionnaires. The content validity is confirmed by an expert panel of nine gastroenterologists. This instrument has desirable psychometric properties. The internal consistency is 0.95 and its test–retest reliability is 0.92. This questionnaire was constructed after literature review and the validity of the instrument and its responsiveness to treatment is also established.[9]

Data Analysis: The data were analyzed using SPSS software (version 15). To analyze the psychometric characteristics of the questionnaire, we used Cronbach's alpha (to assess coordination of items to assess construct), structural validity (correlations of item subscales with items overall), concurrent validity (which showed the P-IBS-QOL assess construct of HRQOL, which was analyzed using Pearson correlations), and an independent t-test (to determine construct validity). Before using the tests, we tested two preassumptions: 1) normality was tested with the Shapiro–Wilk test, and the results confirmed this preassumption ($P > 0.05$); 2) To assess the validity of using the independent t-test, we tested the equality of variances between two groups; the results did not show a significant difference between the scores of the two groups ($P > 0.05$).

RESULTS

Demographic and clinical characteristics of the participants are presented in Table-I. Descriptive statistics (mean and standard deviation of raw

Table-I: Characteristics of study participants.

Variable	*Levels*	*Frequency*	*Percentage*
Gender	Male	55	43
	Female	71	57
Marital status	Single	42	33
	Married	84	67
Education	Lower than high school	31	25
	High school diploma	57	45
	College degree	11	9
	Bachelor's degree and higher	27	21
Subtype	Constipation predominant	42	33
	Diarrhea predominant	51	40
	Mixed	33	27
Severity	Mild	49	39
	Average	57	45
	Severe	20	16

Table-II: Review of descriptive findings on the scale and internal consistency of the items.

Domain	*Mean and standard deviation*	*Items*	*Correlation coefficient of subscales scale*	*Correlation coefficient of overall*
Dysphoria	61.8 (25)	1	*0.59	*0.49
		6	*0.82	*0.53
		7	*0.70	*0.48
		9	*0.75	*0.62
		10	*0.64	*0.64
		16	*0.65	*0.61
		30	*0.56	*0.50
Interference with activity	67.8 (19.8)	3	*0.32	*0.24
		18	*0.46	*0.48
		19	*0.46	*0.25
		22	*0.42	*0.39
		27	*0.36	*0.35
		29	*0.48	*0.28
		31	*0.17	*0.52
Sexual concern	73.5 (25)	12	*0.85	*0.36
		20	*0.92	*0.28
Health worry	60.3 (25.5)	4	*0.60	*0.40
		15	*0.44	*0.43
		32	*0.53	*0.59
Food avoidance	42.6 (24.6)	11	*0.66	0.10
		23	*0.49	*0.37
		28	*0.34	*0.18
Social reaction	44 (27.8)	2	*0.56	*0.39
		14	*0.71	*0.50
		17	*0.62	*0.38
		34	*0.84	*0.49
Relationships	42.6 (24.6)	8	*0.58	*0.46
		24	*0.69	*0.27
		33	*0.64	*0.88
Body image	28.2 (21.3)	5	*0.62	*0.31
		21	*0.47	0.11
		25	*0.80	*0.38
		26	*0.68	*0.74
Total score	40.4 (12.3)			

*Significant coefficients (P < 0.05)

scores) and correlation coefficients of each item and its subscales and for the overall test are presented in Table-II. The results show that most item–subscale correlations exceeded 0.55, and item–overall correlations exceeded 0.35 (with the exception of correlation coefficients of items 11, 21, and 32).

The internal consistency coefficients of the eight subscales and the overall scale are presented in Table-III. With regard to concurrent validity between the main questionnaire and the other questionnaires whose psychometric characteristics, the correlation coefficient was 0.61, significant at the 0.01 level, and the questionnaire had acceptable concurrent validity ($r = 0.61$, $P < 0.05$).

In order to assess the construct validity of the quality of life questionnaire, raw scores of the eight subscales and the total score of the questionnaire for the patients (n = 40) and healthy participants (n = 40) were compared using the independent t-test. The results showed significant differences between the mean raw scores for seven subscales (the exception was the body image subscale) and the overall scale for the two groups ($P < 0.05$). The results are presented in Table-IV.

DISCUSSION

The IBS-QOL-34 was developed in 1998 by Patrick and Drossman and has special sensitivity to various treatments; it has been translated into several languages and the translated versions are valid and reliable. To prepare a Persian version of IBS-QOL, we translated the original questionnaire into Persian and tested its validity and internal consistency.

We look first at the relationships of the items with the subscales and total scores. The magnitudes of the correlations showed that most item–subscale correlations exceeded 0.55 (i.e., almost 0.6, which is a satisfactory correlation). Item 20 had the highest correlation and item 31 had the lowest. Thus, most correlations were significant, which means that the

Table-III: Internal consistency indices (Cronbach's alpha) of subscales and overall scale in the Persian, American, European, and Japanese versions of IBS-QOL.

Domain Subscales	*Persian version (n = 126)*	*American version (n = 155)*	*European version (n = 35)*	*Japanese version (n = 49)*
Dysphoria	0.88	0.92	0.94	0.94
Interference with activity	0.67	0.84	0.82	0.86
Body image	0.72	0.75	0.79	0.56
Health worry	0.57	0.70	0.74	0.48
Food avoidance	0.52	0.76	0.83	0.83
Social reaction	0.71	0.74	0.84	0.76
Sexual	0.76	0.83	0.75	0.61
Relationships	0.62	0.65	0.77	0.74
Overall scale	0.93	0.95	0.96	0.96

Table-IV: Results of independent t-test assessing the construct validity of IBS-QOL of in healthy participants and patients.

Subscales	*Mean difference*	*Significance level*
Dysphoria	7.55	0.000*
Body image	3.27	0.002*
Food avoidance	1.49	0.087
Sexual	2.85	0.000*
Relationships	4.87	0.000*
Interference with activity	2.15	*0.021
Health worry	2.03	*0.034
Social reaction	3.62	*0.000
Overall scale	28	*0.000

*Significant difference ($P < 0.05$)

items show an acceptable statistical relationship. Another important finding is that the item–subscale correlations were higher than the item–overall correlations. This is an acceptable finding, meaning that in general the questionnaire has a desirable consistency and internal structure.

To assess the internal consistency of the subscales, we used Cronbach's alpha. The subscale food avoidance had the lowest internal consistency (0.52) and dysphoria the highest (0.88). The minimum alpha considered acceptable for questionnaire validation is 0.7.[22] Cronbach's alpha for subscale relationships, health worry, food avoidance, and interference with activity was lower than the acceptable value of 0.7. This may be explained by the lower conceptual relationships of these subscale items compared with other subscales. This result is consistent with the results of Kanazawa[17] and Patrick and Drossman.[21] However, the subscale of health worry in the Persian, American, European, and Japanese versions of the questionnaire had a low alpha. This may be related to the content of questions on this subscale, which could be replaced by ideas expressed by these patients regarding their health, such as "this disease leads to progressive complications and brings my death closer" or "this disease will never be treated" (only in Persian culture). This finding is understandable in light of the equation for Cronbach's alpha ($\sqrt{a} = \frac{J}{J-1}\left[1-\frac{\sum S^2 j}{S^2}\right]$). The magnitude of Cronbach's alpha has a direct relationship with the number of items; therefore, the dysphoria subscale (with eight items) has a higher alpha than the food avoidance subscale (three items). In the American, European, and Japanese versions of IBS-QOL, the dysphoria subscale has the highest alpha (Table-III).

Moreover, the high internal consistency coefficients of the dysphoria subscale and the overall questionnaire (sum score) supports the idea that Cronbach's alpha is greatly affected by the number of questions in a questionnaire. An absolute conclusion cannot be made by comparing the internal consistency indices of the Persian, American, European, and Japanese versions. In the Persian version, the food avoidance subscale has the lowest internal validity, while in the American, European, and Japanese versions the relationship and health worry subscales have the lowest internal validity; however, the internal consistency of the questionnaire is acceptable and relatively high.

Quality of life is a complicated concept which is affected by social and cultural factors. Social reactions of people around patients towards their complaints, patients' attitudes, and body image and the effects of disease on body image are greatly influenced by the social culture and its values and norms. To assess concurrent validity, a completely specific instrument (rather than a general instrument) was needed. For this purpose we selected IBS-QOL-36, which was developed and validated by Groll and colleagues. These two questionnaires overlap in some dimensions and constructs. The questionnaire was translated and administered to 40 IBS patients. The results showed that the scale has high internal consistency (0/87). Assessment of concurrent validity showed a significant and relatively high positive correlation coefficient between the two questionnaires, which means that this instrument can be used safely for assessing quality of life.

The results of the construct validity assessment showed that the questionnaire items specifically assess patients' problems in daily life. This means that the questions are designed with special consideration of the patients' specific problems.

In another study, the construct validity of this questionnaire was confirmed in distinction between the quality of life of IBS patients and patients with other gastroenterological disorders.[10] Indeed, using this instrument for full diagnosis needs determination of the optimal cut-off point as well as its specificity and sensitivity. Factor analysis (the KMO coefficient was not satisfied) was not used in this research. It is recommended that future research in this field should use confirmatory factor analysis (CFA) to assess the construct validity and subscales of the questionnaire.

Limitation and recommendation: Because of time limitation it was not possible to determine the

test–retest reliability and responsiveness to treatment of P-IBS-QOL. However, one doctoral thesis (from the psychology department of Isfahan University), titled "The efficacy of relaxation therapy, cognitive-behavioral therapy and life style training on the HRQOL of IBS patients" used P-IBS-QOL as an instrument, and the results of MANCOVA showed significant differences between four experimental groups and a control group.[23] This means P-TBS-QOL has adequate sensitivity to therapeutic changes. We suggest that the test–retest reliability of P-IBS-QOL should be determined at different intervals in the next validation of this version. Also, experimental plans must be designed to consider the rate of responsiveness of IBS-QOL to therapeutic interventions such as drug therapy, CBT, and psychoeducation. Another limitation of this study was that although we tried to select the research sample with regard to the age range and gender distribution of the population, because of the high prevalence of IBS the sample size was relatively small. This factor must be considered in future research on this version of the questionnaire.

CONCLUSION

In conclusion, the P-IBS-QOL appears to be a valid and reliable scale that can be used to assess QOL specifically in IBS patients in the Persian population. This version of IBS-QOL has an acceptable and desirable internal structure, internal consistency, and construct validity. P-IBS-QOL can be used in clinical and research trails.

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